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EXAMINER

LEUNG, JENNIFER A

ART UNIT	PAPER NUMBER
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1764

DATE MAILED: 06/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/733,436

Applicant(s)

FITCHMUN, MARK

Examiner

Jennifer A. Leung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-19 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-3 and 5-21 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's Amendment filed on April 21, 2003 has been received and carefully considered. The submitted changes to the specification are acceptable. Claim 4 has been cancelled. Claim 20 is withdrawn from consideration. Claims 1-3, 5-19 and 21 remain active.

### ***Specification***

2. The disclosure is objected to because of the following informalities:

- On page 6, lines 29 and 31, "phosphonate" should be changed to -- phosphate --.

Appropriate correction is required.

3. It is suggested by the Examiner that the following be inserted into the specification, since such disclosure is considered essential to the practice of the invention, but is not included in the specification:

- On page 4, after line 12, -- The term "radioactive waste" as used herein refers to a radioactive isotope selected from the group consisting of  $^{125}\text{I}$ ,  $^{131}\text{I}$ ,  $^{36}\text{Cl}$ ,  $^{33}\text{P}$ ,  $^{32}\text{P}$ ,  $^{35}\text{S}$ ,  $^{18}\text{F}$ ,  $^{15}\text{O}$ ,  $^{14}\text{C}$ ,  $^{13}\text{N}$ ,  $^{11}\text{C}$  and  $^3\text{H}$ . --.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 14, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. (U.S. 4,081,402).

Regarding claims 14 and 16-18 Levy et al. disclose a composition comprising an

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absorbent matrix (i.e. hydrophilic polymer or hydrogel matrix; column 4, line 37-column 6, line 46), a humectant (i.e. ethylene glycol, glycerol; column 4, lines 59-65), a pH-stabilizing agent (i.e. dibasic potassium phosphate; column 13, lines 38-40; column 14, lines 18-24) and an absorbent material (i.e. activated carbon, activated charcoal derived from wood charcoal; ion exchange resins; column 7, lines 31-55).

Instant claims 14, 16-18 read on the composition of Levy et al.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. 4,081,402) in view of Lennon et al. (U.S. 4,999,163).

Regarding claims 1 and 21, Levy et al. disclose an absorbent matrix (i.e. hydrophilic polymer or hydrogel matrix; column 4, line 37-column 6, line 46) comprising a humectant (i.e. ethylene glycol, glycerol; column 4, lines 59-65), a pH-stabilizing agent (i.e. phosphate buffer of pH 7.6; column 13, lines 38-40; column 14, lines 18-24) and an absorbent material (i.e. activated carbon, ion exchange resins; column 7, lines 31-55). Levy et al. further disclose the absorbent matrix is insertable into at least one receptacle having an open end (i.e. group of test tubes; FIG. 2; column 11, lines 35-50; column 13, lines 34-53). Although Levy et al. are silent as to a lid and a means for affixing the lid securely to the receptacle, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide such to the receptacle of Levy et al., because the use lids for sealing the contents of a receptacle, such as an absorbent, is well known in the art, as evidenced by Lennon et al. (i.e. receptacle **12** comprising a lid element

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30, with means for affixing the lid securely to the receptacle; Abstract; FIG. 2).

Regarding claims 2 and 3, Levy et al. disclose the apparatus may be used for the radioimmunoassay of antigens with  $^{125}\text{I}$  or  $^3\text{H}$  (column 13, line 3 to column 15, line 12).

Regarding claim 5, Levy et al. disclose the absorbent matrix may be deposited within a cylinder or article constructed of inert plastic (column 2, lines 60-65). Also, selection of plastic is well known in the art, as evidenced by Lennon et al. (column 6, lines 38-44).

Regarding claim 6, Levy et al. further disclose said absorbent matrix is constructed of one or more synthetic materials (column 5, line 19 to column 6, line 46).

Regarding claim 7, although Levy et al. are silent as to the absorbent matrix comprising a natural material, it would have been obvious design choice for one of ordinary skill in the art at the time the invention was made to select a natural material for the absorbent matrix in the modified apparatus of Levy et al. because the use of natural materials as absorbent matrices is well known in the art, as evidenced by Lennon et al. (column 6, lines 49-57).

Regarding claim 8, Levy et al. disclose synthetic materials comprising polyacrylamide (column 5, lines 34-44), hydrophilic polymers (column 5, line 19+) and prior art use of dextrans (column 2, lines 3-14).

Regarding claim 9, Levy et al. are silent as to whether the absorbent matrix may comprise unidirectional cotton fibers. Lennon et al. (column 4, line 53 to column 5, line 2) teach an absorbent plug comprising conventionally known materials such as cotton fibers and having capillary passages which are both transverse to and generally parallel to the surfaces at the upper and lower ends of the plug. The plug inherently comprises unidirectional fibers, as in the stated examples of a cigarette filter or tampon (column 6, line 45 to column 7, line 2). It would have

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been obvious for one of ordinary skill in the art at the time the invention was made to select unidirectional cotton fibers for the absorbent matrix in the modified apparatus of Lennon et al. because such cotton fibers are capable of absorbing aqueous materials while possessing sufficient structural integrity, as taught by Lennon et al.

Regarding claims 10-11, Levy et al. disclose the pH-stabilizing agent may comprise a dibasic phosphate salt (i.e. dibasic potassium phosphate; column 14, lines 18-24).

Regarding claim 12, Levy et al. disclose said adsorbent material may comprise polymeric resins (column 7, line 54- column 9, line 23).

Regarding claim 13, Levy et al. further disclose said adsorbent material may comprise activated charcoal (i.e. activated carbon derived from wood charcoal; column 7, lines 44-53).

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. 4,081,402), as applied to claim 14 above, and further in view of Lennon et al (U.S. 4,999,163).

Levy et al. are silent as to the absorbent matrix comprising unidirectional cotton fibers. The same comments with respect to Lennon et al. apply (see claim 9 above).

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. 4,081,402) in view of Dean (*Lange's Handbook of Chemistry*).

Levy et al. disclose the absorbent matrix may comprise glycerol (column 4, lines 61-65), dibasic potassium phosphate (column 14, lines 18-24) and activated charcoal (column 7, lines 44-53). Although Levy et al. are silent as to disodium phosphate salts, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to substitute disodium phosphate salts for dibasic potassium phosphate in the composition of Levy et al., since both compounds are capable of stabilizing pH and are known equivalents for

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achieving a specific pH. As illustrated by Dean, use of disodium phosphate salt, as well as dibasic potassium phosphate, is well known in the art (Table 8.14, columns 6 and 7). In any event, the substitution of known equivalents involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958).

Levy et al. are silent as to specifically about 3-20 parts glycerol, 1-10 parts dibasic potassium phosphate (equivalent to disodium phosphate) and 0.5 - 10 parts activated charcoal. However, Levy et al. disclose the amount of glycerol added will depend on the level of hydration desired (i.e. partially or fully hydrated; column 4, lines 59-65) and therefore it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to select an appropriate amount of glycerol, depending on the intended use. Levy et al. further disclose the parts of pH stabilizer will depend on the desired pH level (i.e. a pH of 7.6 in Example 2; column 13, line 3 to column 14, line 44), and therefore it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to select an appropriate amount of stabilizer to achieve a specific pH level, depending on the intended use. Finally, Levy et al. disclose the amount of activated charcoal in the composition will depend on the dimensions of the matrix (i.e. FASTAB, added in step 4; column 13, lines 34-53). In Example 1, Levy et al. disclose the use of 20 grams of activated charcoal for forming disks of approximately 8 mm diameter and 4 mm thickness (column 12, lines 11-42), which are later inserted into test tubes. Therefore, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to modify the parts of activated charcoal to be about 0.5-10 parts by simply modifying the dimensions of the punched disks,

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depending on the intended use, since it has been held that changes in size involve only ordinary skill in the art. *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955).

### ***Response to Arguments***

8. Applicant's arguments filed on April 21, 2003 with respect to claims 1-3, 5-19 and 21 have been fully considered but they are not persuasive.

Applicants argue,

“the hydrophilic absorbents of Levy et al. were not designed to reduce the volatility of radioactive waste, they are merely compositions for removal of undesirable low molecular weight compounds from a solution assay.” (page 9, second paragraph)

Regarding the “pH-stabilizing agent”, applicants argue that Levy et al. do not teach,

“the need for a pH stabilizing agent in their composition to reduce the volatility of radioactive (<sup>125</sup>I) waste product from the reaction. It is merely an artifact of the need to buffer the biological sample being tested to prevent undesirable reactions that could adversely effect the sample and the results of the assay.” (page 9, third paragraph).

Applicants further iterate,

“No where in Levy et al. do they teach the purpose and need for a pH-stabilizing agent in their compositions.” (page 9, last paragraph).

In response to applicant's arguments that the purpose and need for providing the pH-stabilizing agent in the reference of Levy et al. are not identical to the purpose and need for providing the pH-stabilizing agent in the instant invention, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure



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is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

**Conclusion**

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

\* \* \*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is 703-305-4951. The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola can be reached on 703-308-6824. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer A. Leung  
June 20, 2003 *jal*

*Hien Tran*

**HIEN TRAN  
PRIMARY EXAMINER**